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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA; the States of :  
CALIFORNIA, COLORADO, CONNECTICUT, :  
DELAWARE, FLORIDA, GEORGIA, HAWAII, :  
ILLINOIS, INDIANA, LOUISIANA, :  
MARYLAND, MASSACHUSETTS, MICHIGAN, :  
MINNESOTA, MONTANA, NEVADA, :  
NEW HAMPSHIRE, NEW JERSEY, NEW :  
MEXICO, NEW YORK, NORTH :  
CAROLINA, OKLAHOMA, RHODE :  
ISLAND, TENNESSEE, TEXAS, VIRGINIA, :  
WISCONSIN; the DISTRICT OF COLUMBIA; :  
the CITY OF CHICAGO, and the CITY OF :  
NEW YORK, *ex rel.* OSWALD BILOTTA, :

Plaintiffs and Relator, :

v. :

NOVARTIS PHARMACEUTICALS :  
CORPORATION, :

Defendant. :

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UNITED STATES OF AMERICA, :

Plaintiff, :

v. :

NOVARTIS PHARMACEUTICALS CORP., :

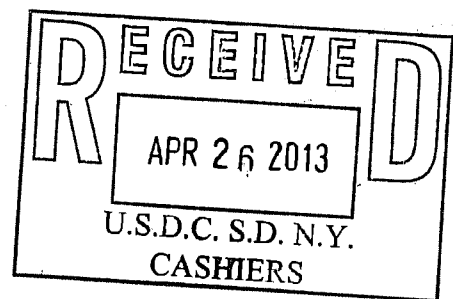
Defendant. :  
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ECF CASE

Case No. 11 Civ. 0071 (PGG)

**COMPLAINT IN INTERVENTION  
OF THE UNITED STATES OF  
AMERICA**

JURY TRIAL DEMANDED



Plaintiff United States of America (the “United States” or the “Government”), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, brings this action against Novartis Pharmaceuticals Corporation (“Novartis”), alleging upon information and belief as follows:

**PRELIMINARY STATEMENT**

1. This is a civil action brought by the United States against Novartis under the False Claims Act, 31 U.S.C. §§ 3729-33 (the “FCA”), and the common law to recover treble damages sustained by, and civil penalties and restitution owed to, the United States based on Novartis’s violations of the Anti-Kickback Statute (the “AKS”), 42 U.S.C. § 1320a-7b(b), for paying kickbacks to doctors to induce them to prescribe certain Novartis pharmaceutical products that were reimbursed by federal health care programs. As set forth more fully below, from January 2002 through at least November 2011, Novartis systematically paid doctors to speak about certain of its drugs, including its cardiovascular drugs Lotrel and Valtorna and its diabetes drug Starlix, at events that were often little or nothing more than social occasions for the doctors. The payments to the doctors, and the dinners, were kickbacks to the speakers and the attendees to induce them to write prescriptions for Novartis drugs.

2. According to Novartis’s policies, speaker programs are events at which a doctor is paid to educate other doctors and health care professionals regarding the company’s drugs by presenting slides prepared by the company. In practice, Novartis held thousands of speaker programs all over the country at which few or no slides were shown and the doctors who participated spent little or no time discussing the drug at issue. Instead, Novartis simply wined and dined the doctors at high-end restaurants with astronomical costs, as well as in sports bars, on fishing trips, and at other venues not conducive to an educational program.

3. Novartis's own internal analyses showed that speaker programs had a high return on investment in terms of the additional prescriptions for its drugs written by the doctors who participated in the programs, both as speakers and attendees, with the highest return arising from payments to doctors as "honoraria" for speaking.

4. Novartis was well aware that its speaker programs created opportunities to provide kickbacks to doctors. In September 2010, Novartis entered into a settlement with the U.S. Department of Justice to settle FCA lawsuits based in part on false claims arising from illegal remuneration Novartis had paid to doctors through such mechanisms as speaker programs. The company signed a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services Office of Inspector General agreeing to implement a rigorous compliance program.

5. Yet even after entering into the CIA, Novartis's compliance program was inadequate to prevent illegal payments and other perquisites to doctors in conjunction with Novartis's speaker programs. Novartis did not adequately review its speaker program to determine whether the programs were being used for an illegitimate purpose. Furthermore, although many instances of speaker program abuse were reported to Novartis's compliance department, sanctions for illegal conduct were generally mere slaps on the wrist. In some cases, sales representatives who violated Novartis's own speaker program policies were nevertheless promoted. Even after September 2010, Novartis continued to conduct bogus speaker programs that were simply vehicles for paying kickbacks to doctors in the form of honoraria and expensive meals.

6. By paying kickbacks to doctors, Novartis knowingly has caused the submission of thousands of false claims for payment to federal health care programs, including Medicare,

Medicaid, TRICARE, and the Veterans Administration health care program. Accordingly, Novartis is liable under the FCA for treble damages and penalties for these claims for reimbursement for Lotrel, Valtorna and Stalix, as well as for other Novartis cardiovascular drugs, as discussed in detail below.

### **JURISDICTION AND VENUE**

7. This Court has jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the remaining claims pursuant to 28 U.S.C. § 1345.

8. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because Novartis does business in this district and some of the false or fraudulent acts occurred in this District.

### **PARTIES**

9. Plaintiff is the United States of America suing on its own behalf and on behalf of the United States Department of Health and Human Services (“HHS”), and its component agency, the Centers for Medicare and Medicaid Services (“CMS”) (formerly known as the Health Care Financing Administration), which administers the Medicare and Medicaid programs; the Department of Defense, which administers the TRICARE/CHAMPUS program (TRICARE”); and the Department of Veterans Affairs (“VA”).

10. Relator Oswald Bilotta, a former resident of New York who moved to North Carolina in July 2012, is a former employee of Novartis. In January 2011, Mr. Bilotta filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

11. Defendant Novartis is a subsidiary of Novartis AG, an international pharmaceutical company headquartered in Basel, Switzerland. Novartis, which is headquartered in East Hanover, New Jersey, does business throughout the United States, including in the Southern District of New York.

### **FACTUAL ALLEGATIONS**

#### **I. The Anti-Kickback Statute and the False Claims Act**

12. The FCA establishes liability to the United States for an individual who, or entity that, “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” § 3729(a)(1)(A); or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” § 3729(a)(1)(B).<sup>1</sup> “Knowingly” is defined to include actual knowledge, reckless disregard and deliberate indifference.

§ 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

13. The AKS makes it illegal for individuals or entities to knowingly and willfully “offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care

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<sup>1</sup> In May 2009, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (“FERA”). Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to defendants’ conduct for the entire time period alleged in the complaint by virtue of Section 4(f) of FERA. Section 3279(a)(1)(A), formerly Section 3729(a)(1), of the FCA prior to FERA, and as amended in 1986, applies to conduct on or after May 20, 2009. Section 3729 of the pre-FERA FCA provides, in pertinent part, that:

- (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval . . .

\* \* \*

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

program.” 42 U.S.C. § 1320a-7b(b)(2). Payments by a pharmaceutical company to doctors to induce them to write prescriptions for the company’s pharmaceutical products that are reimbursed by federal health care programs are examples of such illegal remuneration. Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7).

14. The AKS arose out of congressional concern that remuneration given to those who can influence health care decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the Medicare and Medicaid programs, among other federal health care programs, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Publ. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Publ. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

15. As codified in the Patient Protection and Affordable Care Act of 2010 (“PPACA”), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].”

16. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify “that all claims resulting from illegal kickbacks are considered false

claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves.” 155 Cong. Rec. S10854.

17. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under the federal health care programs.

18. By providing kickbacks to physicians to induce them to prescribe certain of Novartis’s pharmaceutical products, Novartis has caused false claims to be submitted to federal health care programs.

19. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties are \$5,500 to \$11,000 for violations, such as those alleged here, occurring on or after September 29, 1999.

## **II. The Federal Health Care Programs**

20. For the drugs at issue in this case, generally, when a physician prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

21. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

22. **Medicare.** Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395 *et seq.* (“Medicare Program”). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. All persons enrolled in

Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, the Centers for Medicare and Medicaid Services (“CMS”), contracts with private companies (or “sponsors”) authorized to sell Part D insurance coverage. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts.

23. Medicare enters into provider agreements with physicians to establish their eligibility to participate in the program. To be eligible for payment under the program, including for prescriptions for pharmaceutical products, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws.

24. On the Medicare provider enrollment agreement, the “Certification Statement” that the medical provider signs states: “You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below.” Those requirements include:

I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier’s compliance with all applicable conditions of participation in Medicare.

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I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

CMS Form 855I.



25. In addition, when pharmaceutical products are reimbursed under Medicare Part D, Part D sponsors must certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, the Anti-Kickback Statute. 42 C.F.R. § 423.505(h)(1).

26. CMS regulations require that all subcontracts between Part D sponsors and pharmacies contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

27. **Medicaid.** Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent.

28. The Medicaid programs of all states reimburse for prescription drugs. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which

provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

29. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. For example, the New York regulatory regime provides that an “overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake.” N.Y. Comp. Codes R. & Regs. Title 18 § 518.1(c). “Unacceptable practice” is defined to include “[b]ribes and kickbacks,” *id.* § 515.2(b)(5), and lists within this category both “soliciting or receiving,” *id.* § 515.2(b)(5)(ii), and “offering or paying,” *id.* § 515.2(b)(5)(iv), “either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program,” *id.* § 515.2(b)(5)(ii), (iv). New York’s anti-kickback statute forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law §§ 366–d –f.

30. States also require certifications by physicians as a condition of providing Medicaid reimbursement for the prescriptions they write. These certifications include compliance with the Anti-Kickback Statute, among other federal health care laws.

31. A provider who participates in the Medicaid program must sign an agreement with his or her state that certifies compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

32. **TRICARE.** TRICARE, administered by the Department of Defense (“DOD”), is the United States military’s health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. TRICARE operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits. Military prescription drug benefits are provided through three programs: military treatment facility outpatient pharmacies, TRICARE contractor retail pharmacies, and a national contractor’s mail-order service.

33. TRICARE requires physicians to certify to compliance with the Anti-Kickback Statute, among other federal health care laws.

34. **Veterans Administration Health Care.** The Department of Veteran Affairs (“VA”) maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are purchased directly or indirectly by the VA and dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans.

### **III. Novartis Was Well Aware That Speaker Programs Without Sufficient Controls Could Violate the Anti-Kickback Statute**

35. Novartis recognized the need to comply with the AKS in promoting its drugs to health care professionals. Novartis’s Ethics and Compliance (“E&C”) Policies, originally issued in 2003 and reissued in January 2006 and in subsequent years, provide that:

The Federal Anti-kickback Statute makes it illegal to knowingly and willfully provide any “remuneration” in return for:

- (1) referring a person to another person for items or services covered under federal health care programs; or
- (2) purchasing or recommending the purchase of any good or service which is paid for by federal health care programs.

“Remuneration” is defined very broadly and includes any item of value which is provided with the *intent to induce* the actions described above. Essentially, this law, and similar state statutes, prohibits bribes and kickbacks. The federal statute applies to payments made under virtually any federal healthcare program – not just Medicare and Medicaid. Note again that many state statutes similarly prohibit such activities.

Under the Anti-kickback Statute, it is illegal to *solicit* (ask for) or *receive* kickbacks, as well as to *offer* to pay a kickback. Any of these actions constitutes a felony and is punishable by a fine up to \$25,000 per violation and imprisonment up to five years, or both. In addition, the government may impose civil fines and may terminate an entity’s right to provide products and services to patients whose care is paid for by government programs.

(Emphasis added in 2006 version of the Novartis E&C Policies and in subsequent versions.)

Novartis’s E&C Policies also acknowledge that “[j]udicial and administrative interpretations of this law have been very broad” and that “[t]he statute is violated if even one purpose (as opposed to a primary or sole purpose) is to induce the Healthcare Provider to prescribe its product.”

Novartis’s E&C Policies also note that the “government will infer” that a pharmaceutical company has an intent to induce a healthcare provider to prescribe its product when a payment or other benefit to a provider for a purported service “lacks substance.”

36. Novartis’s E&C Policies also recognize that “relationships with Healthcare Professionals are intended to benefit patients and to enhance the practice of medicine.” The policies state that “[i]nteractions with Healthcare Professionals should be focused on providing information about our products, providing scientific and educational information and supporting

medical research and education in venues that are conducive to such discussions.” They further note that inviting health care professionals to events such as fishing trips “is inappropriate and is not permitted.”

37. This language in Novartis’s E&C Policies parallels language in the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals (“the PhRMA Code”) issued in 2004 and reissued in 2009. Novartis, along with other major pharmaceutical companies, is a member of PhRMA, a signatory to the Code and has announced its intention to abide by the Code. In addition, Novartis has expressly certified that it is in compliance with the Code. The PhRMA Code provides that “[i]nteractions” between pharmaceutical company employees and health care professionals “should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.”

38. In addition to setting forth general rules, Novartis’s E&C Policies also contain rules specific to speaker programs. Starting in 2003 and continuing through the present, Novartis’s E&C Policies have provided that speaker programs must be held at venues that are “conducive to an exchange of medical information.” As of 2006, Novartis’s E&C Policies have also provided that “[f]ood and beverages are intended to be ancillary to meaningful discussion,” must be in “modest amounts (quantity and cost),” and must be “incidental to a professional discussion or interaction.” (Emphasis in original.)

39. These policies parallel the PhRMA Code, which states that:

In connection with [speaker programs and other promotional events], it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are modest as judged by local standards; (b) are not part of an

entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.

In addition, the PhRMA Code provides that “[c]ompanies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.” Further, it provides that “companies should not provide any entertainment or recreational items, such as . . . vacation trips, to any healthcare professional who is not a salaried employee of the company.”

40. In further recognition that speaker programs must have a legitimate purpose to comply with the AKS, at all times relevant to the complaint, since 2003 and continuing through the present, Novartis’s E&C Policies have also required that speakers make a presentation using a slide deck provided to them by Novartis. In addition, Novartis’s E&C Policies provide that programs must have at least three health care professionals in attendance and that at least one Novartis sales representative must be present at every speaker program. Since at least 2008, Novartis’s E&C Policies have also provided that doctors or other practitioners from the speaker’s own practice cannot be included in determining whether a program has at least the minimum three attendees.

#### **IV. In September 2010, Novartis Entered into a Settlement With the Federal Government and the States for Speaker Program Fraud, Among Other Unlawful Activity, and Novartis Became Subject to a Corporate Integrity Agreement**

41. On September 27, 2010, Novartis settled FCA claims with the federal government and the states, based in part on AKS violations. The settlement stated that Novartis had “provided illegal remuneration, through mechanisms such as speaker programs, advisory boards, and gifts (including entertainment, travel and meals), to health care professionals to induce them to promote and prescribe the drugs Diovan, Zelnorm, Sandostatin, Exforge, and Tekturna, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b).”

42. At the same time as the settlement, Novartis also entered into a CIA with the Office of Inspector General of the Department of Health and Human Services. The CIA requires Novartis, among other things, to “ensure that [its] Policies and Procedures address . . . appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the federal anti-kickback statute . . . and the False Claims Act . . . .” CIA at Section III(B)(3)(c). The CIA also provides that Novartis’s compliance policies and procedures must “address . . . programs to educate sales representatives, including but not limited to presentations by [health care professionals] . . . .” and “be designed to ensure that the programs are used for legitimate and lawful purposes . . . .” *Id.* at (3)(l).

43. The CIA also requires that Novartis’s compliance policies “address . . . compensation (including through salaries, bonuses, and contests) for . . . sales representatives” and be “designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Novartis’ Government Reimbursed Products . . . .” *Id.* at (3)(q).

## **V. The Drugs in Novartis’s Cardiovascular Division**

44. At all times relevant to the complaint, Novartis sold the drugs Lotrel, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, Exforge HCT, Valtorna, Tekamlo, and Starlix as part of its cardiovascular (“CV”) division.

45. At all times relevant to the complaint, Novartis sold these drugs through a network of sales representatives who called on health care professionals throughout the United States. The drugs in Novartis’s CV division were promoted together by sales representatives in

various combinations. For example, a sales representative might be assigned to promote Lotrel and Diovan, or Diovan, Tekturna, and Valturna to particular doctors.

46. With the exception of Starlix, each of the drugs was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of hypertension. They were approved on the following dates:

- Lotrel in 1995
- Diovan in 1997
- Diovan HCT in 1998
- Tekturna in 2007
- Exforge in 2007
- Tekturna HCT in 2009
- Exforge HCT in 2009
- Valturna in 2009
- Tekamlo in 2010

47. Starlix was approved by the FDA in October 2003 for the treatment of diabetes.

48. Many of Novartis's CV drugs are closely related from a clinical perspective. For example, Valturna is a combination of Tekturna and Diovan, while Diovan HCT is a combination of Diovan and a diuretic.

**VI. Novartis Created Incentives for Sales Representatives to Use Speaker Programs as Kickbacks Without Sufficient Controls to Prevent Kickbacks from Occurring**

49. From 2001 through at least 2011, Novartis conducted speaker programs as a key component of its promotional activities aimed at increasing sales of its drugs. According to Novartis's data, it spent over \$65 million and conducted more than 38,000 speaker programs for Lotrel, Starlix and Valturna during the period from January 1, 2002 through November 2011. Of



this \$65 million, Novartis spent nearly \$51 million for approximately 29,000 speaker programs on Lotrel between 2002 and 2007, when a generic competitor pharmaceutical product entered the market. For Starlix, Novartis spent nearly \$4 million for approximately 3,200 speaker programs between 2002 and 2007, when a generic competitor pharmaceutical product entered the market. For Valturna, Novartis spent approximately \$11 million for more than 6,500 programs from its approval by the FDA in 2009, until Novartis announced in April 2012 that it would withdraw Valturna from the market in July 2012.

50. At all times relevant to the complaint, the vast majority of speakers for Novartis's speaker programs were nominated by sales representatives, who picked doctors from among those they called on to promote Novartis drugs.

51. According to Noah Puckowitz, director of Novartis's speaker program bureau from June 2008 through May 1, 2012, Novartis approved all speaker nominations by sales representatives as long as the doctor had a valid license and had not been suspended or debarred from the practice of medicine.

52. A much smaller number of speakers, usually prominent doctors known as "key opinion leaders" ("KOLs"), were chosen by the drug's "brand team," an interdisciplinary group of marketing, sales and scientific specialists who were in charge of the overall management of each brand.

53. Sales representatives were compensated in part based on the number of prescriptions written by doctors on their call lists. This created incentives for sales representatives to use speaker programs as a vehicle to pay kickbacks to doctors to increase their compensation.

54. At all times relevant to the complaint, Novartis sales representatives had a quarterly budget for speaker programs, which they were pressured to spend. The evaluation in 2007 of one sales representative in Long Island by her supervisor, a district manager, stated, for example, "I am disappointed that you did not utilize your entire speaker funds again . . . . In 2008, if your territory is not at 100% of speaker fund utilization . . . . you will be put on a coaching plan immediately." Another sales representative's evaluation in Long Island in 2007 contained identical language.

55. Novartis used these speaker programs as remuneration to induce health care professionals to prescribe Novartis's drugs.

56. Speakers were paid each time that they spoke. Their compensation for each program, known as an "honorarium," was based on such factors as whether the speaker was certified in a specialty, was on the faculty of a teaching hospital, or had any publications or leadership roles in a medical association. However, although these factors affected the level of the honorarium a speaker was paid for each program, a doctor did not have to have any of these qualifications to be chosen as a speaker for Novartis. Many of Novartis's speakers on Lotrel and Valtura and other cardiovascular drugs were family practice doctors and internists, not cardiologists who specialized in treating cardiovascular disease. Likewise, many of Novartis's speakers about Starlix were family practice doctors and internists, not nephrologists who specialized in treating diabetes.

57. Speakers were paid an average of between \$750 and \$1500 for each program depending on the leveling factors, with some speakers earning as much as \$3000 per program.

58. In addition to choosing the speakers, sales representatives also selected the attendees at speaker programs and were responsible for inviting them to the programs. As in the

case of speakers, sales representatives generally chose attendees from the doctors on their call lists.

59. At all times relevant to the complaint, sales representatives selected the speaker, the topic of the program, and the date for the program. Sales representatives also selected the venues for speaker programs.

60. At all times relevant to the complaint, sales representatives scheduled programs for speakers in a speaker program computer database. From 2007 on, Novartis's speaker program database was maintained by a vendor, Advanced Health Media ("AHM"), on Novartis's behalf.

61. At all times relevant to the complaint, Novartis placed no limit on the number of programs a doctor could attend or how often a doctor could attend the same program. There was no system control to prevent a sales representative from repeatedly selecting the same doctors on his call list as attendees at speaker programs on exactly the same topics. Nor was there any system control that prevented a sales representative from arranging for the same doctors to take turns speaking and attending each other's programs repeatedly.

62. Novartis's E&C Policies require that a speaker program "have at least three Healthcare Professionals in attendance," although an event can "continue if, despite a good faith effort" fewer than three doctors attend. Novartis's E&C Policies note that sales representatives "should plan on inviting enough participants to ensure that the minimum requirement is met." Sales representatives were required to cancel a program if fewer than three attendees were confirmed prior to a program occurring.

63. In practice, many programs took place with less than three health care professionals in attendance. Moreover, many programs took place with no one in attendance except members of the speaker's own medical practice.

64. The vast majority of Novartis speaker programs run by the sales force were held in restaurants. At all times relevant to the complaint, Novartis sales representatives were required to choose a restaurant that complied with Novartis's E&C Policies on "modest meals." Starting in 2006, Novartis's policy defined modest meals based on locality, with caps of up to \$100-125 per person in major cities such as New York and Los Angeles and \$80-100 in other U.S. locations. The policy noted that "[m]ost business meals are expected to cost substantially less than th[ose] amounts." (Emphasis in original.). In 2010, Novartis changed its policies to make the cap \$125 per person nationwide.

65. In practice these limits could be avoided through attributing amounts over those caps to what Novartis termed an "unmet minimum," which was the difference between a restaurant's minimum spend for an event and the per person charge for the event. For example, if a restaurant had a minimum charge of \$2,000 for an event, but only four people attended it, a sales representative could attribute \$1,500 of the costs of the program, the amount exceeding the \$125 per capita cost for four people, to the "unmet minimum" for the program. This practice, among others, permitted Novartis to spend lavishly on food and alcohol well beyond the purported "modest meal" caps in its written policies.

66. Novartis does not require that a restaurant have a private room to be an acceptable venue for a speaker program. Nor does Novartis require that the restaurant have a quiet atmosphere.

67. In addition, although Novartis's E&C Policies provide that only "[m]odest meals at a *modest* restaurant are . . . acceptable" for speaker programs (emphasis added), Novartis does not prohibit holding programs at restaurants that are high-end for the particular community in which they are located.

68. Novartis had few checks on whether sales representatives reported truthfully on who attended speaker programs they hosted. In many cases, Novartis did not even require signatures on attendance sheets at speaker events.

69. In addition, it was the sales representatives who set up and attended the events who were responsible for reviewing the accuracy of the receipts at venues where speaker programs took place.

70. Sales representatives' supervisors were made aware of each speaker program a sales representative hosted, the attendees who were purportedly present, and other details regarding the program. First line supervisors, called District Managers, and second-line supervisors, called Regional Managers, had access to the speaker program database and received reports regarding speaker programs.

71. In addition, Novartis's management was sent data regarding speaker programs. AHM provided Novartis with monthly reports regarding speaker programs. As part of those reports, as further discussed in Section XI below, Novartis management was notified of numerous instances in which speakers were paid for programs that had indicia of fraud.

## **VII. Many Thousands of Novartis Speaker Programs Lacked Any Legitimate Purpose**

72. Novartis's speaker program data shows that from 2002 through at least 2011, doctors around the country spoke repeatedly to the same attendees on exactly the same topics. The doctors in these clusters took turns in the roles of speaker and attendee, with doctors

repeatedly attending programs regarding the very same topics they had spoken about. Few or no slides were shown at many of these programs.

73. At each of these events, Novartis paid the speaker an honorarium between \$500 and \$3,000, and Novartis paid the tab at the locale or restaurant at which the dinner took place.

74. **Brooklyn, New York.** For example, an internist in Brooklyn, New York, was the speaker at the same program on Valtorna, a presentation entitled "Blood Pressure Efficacy with More Comprehensive RAAS Inhibition Versus an ARB," ten times from July 2010 to October 2011, with the same three doctors present at nine of the events. Likewise, that same speaker and several of the other doctors who attended her Valtorna events also took turns speaking to each other repeatedly on a Lotrel topic, "Aggressive Strategies for Lowering BP in At-Risk Patients," in 2007. A Novartis sales representative was present at each of these events, and five of the Valtorna events were hosted by the same sales representative.

75. **Bronx, New York.** Similarly, a doctor in the Bronx, New York, spoke on the same Valtorna topic four times from November 2010 to September 2011, with one doctor attending all four times and two doctors attending three times. The speaker also attended that same program three times between April 2010 and September 2011 with many of the same doctors to whom he also gave that program. At many of the programs involving this cluster of doctors no slide presentation was shown to the attendees.

76. The Novartis sales representatives who were present at these programs told the doctors not to present the slides.

77. **Tallahassee, Florida.** Likewise, a doctor in Tallahassee, Florida, was paid \$3,750 for speaking on the same Lotrel topic five times in a nine-month period in 2006-2007 with the same four doctors repeatedly in attendance. One of these doctors attended four of the

events, including two programs that were only one week apart. Another attended three events, including two programs that were only a week apart. At one event, there was only one attendee, a doctor who repeatedly attended the same program.

78. The Tallahassee doctor was also paid \$3,250 for speaking repeatedly on another Lotrel topic, “Rationale for Combination Therapy in the Treatment of Hypertension” (hereinafter “Rationale for Combination Therapy”), three times in early 2005 with the same two doctors in attendance at all three programs and three other doctors in attendance at two. Despite having spoken on the topic, he also attended a program, given by one of the attendees at his programs, on the very same topic during that period. Overall, Novartis’s data shows that the same six doctors attended the same program collectively 23 times in six months.<sup>2</sup>

79. Specifically, regarding this Lotrel topic and this cluster of doctors:

- On February 1, 2005, one doctor presented “Rationale for Combination Therapy,” and five other doctors attended.
- On February 8, 2005, the same speaker attended a presentation of “Rationale for Combination Therapy” by one of the attendees at his programs even though he had presented that program one week earlier, on February 1, 2005, with that doctor as an attendee. Also present at both events were three of the doctors who had attended the program on February 1, 2005.
- On March 9, 2005, the same five doctors who attended the February 1 and February 8 programs again attended “Rationale for Combination Therapy,” with the same doctor as the speaker.

80. In addition, the speaker at the February 1, 2005 program was paid to speak on a third Lotrel topic, “Using Combination Therapy and Optimizing Treatment of Hypertension,” five times in an eleven-month period in 2005 and 2006 with many of those same doctors in attendance at each of the programs.

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<sup>2</sup> The term “collectively” is used in this complaint to indicate the total number of instances of attendance by attendees at an event, not including the speaker.

81. One of the doctors in this cluster was paid between \$50,000 and \$75,000 by Novartis for speaker programs from October 2003 to May 2011.

82. At many of the speaker programs in which these Tallahassee doctors participated, no slides were presented, particularly when, as often occurred, there were only a small number of attendees at the programs. Even when slides were shown at a program, the speaker often would do a truncated version of the slides.

83. At many of the speaker programs involving this cluster, conversation about the drug was a very small part of the event. The doctors mostly talked about other things.

84. ***Baltimore, Maryland.*** In metropolitan Baltimore, Maryland, the same four doctors attended speaker programs together on the same two Lotrel topics, “Aggressive Strategies for Lowering BP in At-Risk Patients” and “Achieving Blood Pressure Goal in More Patients by Using More Effective Drug Combinations,” collectively 27 times during the period from August 2005 through May 2007, with one of the doctors as the speaker at all but one of the events. The speakers gave little or no presentation at these events and often would just give the drug at issue a token mention at the programs. The Novartis sales representatives who were present did not object.

85. ***Union, New Jersey.*** In the Union area in New Jersey, the same three doctors attended speaker programs on the same Valtorna topic, “Blood Pressure Efficacy With More Comprehensive RAAS Inhibition Versus an ARB,” collectively 23 times on eight dates during the period June 2010 through November 2011. In that time frame, one doctor purportedly gave all eight presentations. Seven of these eight events were attended by the same three doctors, with no others in attendance.



86. In addition, those same three doctors collectively attended speaker programs together on the two Lotrel topics, “New Perspectives on the Use of Combination Therapy in HTN: The Challenge of Getting to Goal” and “Using Combination Therapy and Optimizing Treatment of Hypertension,” and a Starlix topic, “The Importance of Meal Time in Lowering HbA1c,” 22 times on ten dates during the period from October 2004 through August 2007. The speaker for all ten events was the same doctor who spoke at all eight presentations on “Blood Pressure Efficacy with More Comprehensive RAAS Inhibition Versus an ARB.”

87. These programs typically had an average of only three or four people in attendance and sometimes as few as two people. The programs were usually attended by the same people, even if, as was often the case, they had attended the same program only weeks earlier. The speaker did not show any slides at the programs at least half the time and sometimes would do an abbreviated slide presentation, skipping some slides and fast forwarding through others. Far from objecting, the vast majority of the time the Novartis sales representatives who were present at the events indicated that they were glad that the program was just a dinner party instead of a genuine speaker program.

88. *Edgewater, New Jersey.* Another cluster of seven doctors in Edgewater, New Jersey, collectively attended speaker programs on the same Valtorna topic 33 times on ten dates during the ten-month period from March 2010 through December 2010, with the doctors taking turns as speaker and attendees. One of the doctors was paid as the speaker on the topic three times and attended programs on that topic seven times, and another doctor in the cluster was paid to speak on the same topic four times and attended programs on the same topic four times, including two instances in which he spoke on the topic and then attended the event within the following two weeks. Those same seven doctors collectively attended speaker programs on

another Valtorna topic, "Treatment Decisions: A New Choice in Antihypertensive Treatment," 21 times on five dates in the five-month period from November 2009 through March 2010. There were two instances in which one of the doctors spoke on the topic and attended the event within the following week. In addition, the two doctors who took turns as speaker, as well as two other doctors, collectively attended speaker programs on a Lotrel topic, "Using Combination Therapy and Optimizing Treatment of Hypertension," ten times on three dates during the four-month period from May 2005 through August 2005.

89. Instead of going through the slides, the doctors would sometimes just talk amongst themselves. Sales representatives were present at these events and did not require the doctors to show the slides.

90. *East Orange, New Jersey.* Another cluster of doctors in the East Orange area of New Jersey, consisting of four doctors, collectively attended speaker programs on the same Valtorna topic nine times in a five-month period between June 2010 and October 2010. One of the doctors who was paid as the speaker at these programs received over \$43,000 from Novartis for programs on Lotrel, Valtorna and Starlix. Another doctor, who works in the same office as this speaker, attended 12 of her speaker programs. Moreover, between October 2006 and July 2007, Novartis's speaker program records indicate that the two doctors were both paid honoraria, of \$1,500 and \$1,000, respectively, as the speakers at six events at which they purportedly both spoke. Novartis paid both doctors honoraria even though the doctors did not in fact both speak at these events.

91. *Bethlehem, Pennsylvania.* A cluster of four doctors in Bethlehem, Pennsylvania, attended the same Valtorna event, "Blood Pressure Efficacy with More Comprehensive RAAS Inhibition Versus an ARB," collectively 27 times on nine dates between May 2010 and June

2011. One of the doctors was paid to speak at eight of the events. Sales representatives were present at each of these speaker programs and were responsible for inviting the same doctors repeatedly to the same events.

92. ***Pittsburgh, Pennsylvania.*** In Pittsburgh, Pennsylvania, the same five doctors collectively attended speaker programs on the same two Lotrel topics, “Rationale for Combination Therapy,” and “Achieving Healthier BP Goals: Focusing on the Impact of Elevated SBP With Increasing Age,” 14 times on eight dates during the period from October 2004 through November 2005. One of the doctors spoke at seven of the eight events. When there were few attendees at the events, which often occurred, the doctors did not give a slide presentation.

93. Another cluster of doctors in Pittsburgh, Pennsylvania, also repeatedly spoke at and attended the same programs. One of the doctors in this cluster, who was frequently the speaker at these programs, often would not present the slides because the attendees had already seen them before. As to this cluster of doctors, it was common practice not to go through the slides, especially in restaurants without a private room.

94. ***Harrisburg, Pennsylvania.*** In Harrisburg, Pennsylvania, a group of five doctors collectively attended the same Lotrel program, given alternately by all five doctors 64 times between June 2006 and July 2007. Three of these events occurred within eight days of each other in September 2006, with four of the doctors attending or speaking at each of the events. Another three of the events occurred within three weeks of each other in March 2007, with three of the same doctors attending all three programs and one of the same doctors attending two of them. At many programs no presentation was given and the Novartis sales representatives who hosted the events did not object.

95. *Beckley, West Virginia.* Similarly, a cluster of four doctors in the area of Beckley, West Virginia, collectively attended the same Lotrel topic 15 times on five dates over an eight-month period in 2005-2006 with the doctors taking turns as speakers. In addition, that same group of doctors plus two others also took turns speaking to each other repeatedly on several other Lotrel topics during the period 2006-2007. According to Novartis's data, these six doctors made presentations to each other 24 times on the same Lotrel topics during the period 2005 through 2007.

96. No presentation was given at these events when, as was often the case, only a small number of doctors attended. It was difficult to find doctors who were willing to attend events in the Beckley area and the doctors willing to attend were predominantly only doctors who were also paid speakers.

97. *Rockford, Illinois.* In Rockford, Illinois, a group of ten doctors collectively attended the same Valtorna program given by two of the doctors, "Blood Pressure Efficacy with More Comprehensive RAAS Inhibition Versus an ARB," 34 times on 12 dates over an 11-month time period between April 2010 and March 2011. One of the doctors paid to speak on that topic also spoke many times on the Lotrel topic "Aggressive Strategies for Lowering BP in At-Risk Patients," and the same seven doctors, as well as two others, collectively attended the event 53 times on 18 dates between May 2006 and June 2007. One doctor purportedly spoke at 15 of those events, and another spoke at the other three.

**VIII. Many Novartis Speaker Programs Were Merely Social Events and Parties at Which Novartis Lavishly Wined and Dined or Otherwise Entertained the Doctors**

98. Speaker programs were held at high-end restaurants or in circumstances or at locations that were not conducive to a legitimate educational event.

99. ***Fishing trips.*** Many speaker programs were held in circumstances in which it would have been virtually impossible for any presentation to be made. Some Novartis speaker programs in Tallahassee were held on fishing trips off the coast, including trips during 2006. Nobody presented any slides on the fishing trips.

100. Novartis also held a speaker program on a Starlix topic on April 25, 2005 at Timber Wolf Lodge, a salmon fishing lodge in Soldotna, Alaska. The speaker was paid an honorarium of \$750.

101. ***Hooters.*** In addition, Novartis conducted numerous events at various Hooters restaurants. These events were purportedly promotional discussions for doctors at which no one was designated or paid an honorarium as the speaker, called “round table” programs. The events occurred on the following dates in the following locations:

- March 16, 2007 at Hooters in Lexington, KY.
- October 12, 2005 at Hooters in Charleston, WV.
- January 25, 2005 at Hooters in Mobile, AL.
- September 9, 2004 at Hooters in Indianapolis, IN.
- August 25, 2004 at Hooters in Daphne, AL.
- May 30, 2004 at Hooters in Castleton, IN.
- April 27, 2004 at Hooters in Gainesville, FL.

A Novartis sales representative was present at each of these events.

102. ***High-End Restaurants and Sports Bars.*** In addition, many speaker programs were held at high-end restaurants or sports bars, some of them on Friday or Saturday nights. One of these programs, on a Valtorna topic, took place on Saturday, June 26, 2010 – just three months before the CIA was signed – at L20, a restaurant in Chicago. Zagat’s describes L20 as a

“swanky dining room inside Lincoln Park’s Belden-Stratford Hotel that delivers an opulent experience . . . ; tabs may bring tears to your eyes, so many say it’s for special occasions only – unless of course you go on someone else’s dime.” On top of the opulent meal, the speaker was paid \$1,500.

103. One of the doctors present at L20 attended speaker programs on that same Valtorna topic five times and another doctor four times. Another, who attended programs on that same topic three times, was also paid by Novartis as a speaker on the same topic seven times. One of those programs took place on Saturday, September 18, 2010 – just days before the CIA was signed – at Japonais, a restaurant in Chicago. Zagat’s describes it as a “swanky River North hot spot” with a “hip downstairs bar” and a “dreamy riverside terrace” that “some complain [is] painfully noisy . . . but others who don’t mind bringing big money like the energetic buzz.” In addition to enjoying a lavish meal, the speaker was paid \$1,500 for this event.

104. The same speaker at Japonais was paid \$1,500 for a program on the same Valtorna topic on Saturday, July 2, 2011 – ten months after the CIA was signed – at Mastro’s Steakhouse, another high-end restaurant in Chicago. Zagat’s describes it as serving “overflowing martinis and towering seafood appetizers [that] put this decadent and very expensive über-steakhouse near the top of local spots; excellent servers will leave guests pampered and satiated in posh bi-level environs replete with chandeliers and white linens, and live piano music nightly means the bar atmosphere rocks.” Moreover, the dinner was attended by only three doctors, all of whom had already attended that same program multiple times.

105. That same speaker was also paid \$1,500 to give a speaker program on Friday, March 2, 2007, at Billy Barooz, a sports bar in Champaign, Illinois, that advertises itself as having twelve 42-inch flat screen TVs. The bar has no private room.

106. This doctor was also paid to speak at his own office eight times. On one of those occasions, October 21, 2004, only one attendee was present for a program on a Lotrel topic, and the total amount spent on the meal was \$1,000, along with a \$1,000 honorarium to the doctor. On two other occasions there were no attendees present and the doctor was paid a \$500 honorarium for each event.

107. Moreover, many other speaker programs flagrantly violated any concept of a “modest meal” based on the cost. For example, Novartis conducted speaker programs on Lotrel topics for a cluster of doctors in the Washington, D.C. area with the following cost:

- \$2,628 for dinner for seven people (\$375 per person) at The Caucus Room in Washington, D.C. on March 1, 2005. The speaker was paid a \$3,000 honorarium. One of the doctors present attended the same program six times; another attended the same program five times and spoke twice on the topic; and another attended the same program once and spoke four times on the topic.
- \$2,016 for dinner for three people (\$672 per person), including the speaker, at Smith & Wolensky in Washington, D.C., on July 7, 2005. The speaker was paid a \$1,000 honorarium. One of the two attendees was present at the same program at The Caucus Room a few months earlier.
- \$1,719 for dinner for seven people (\$245 per person) at IndeBleu, described in Zagat’s as an “ostentatiously hip” spot for “beautiful people” on March 28, 2006. The speaker was paid a \$1,000 honorarium.
- \$1,145 for dinner for three people (\$381 per person) at Ruth’s Chris Steakhouse in Arlington, Virginia, on October 10, 2006. One of the two attendees was present as an attendee at the same program three times and also spoke on the topic.
- \$517 for dinner for two people (\$258 per person) at Oceanaire in Washington, D.C. on March 21, 2007. The speaker was paid an honorarium of \$1,000. The only attendee had attended the program previously.

108. Novartis also conducted a speaker program on a Lotrel topic on October 11, 2006, at Ruth’s Chris Steakhouse in Indianapolis, Indiana, for two attendees, with a meal cost of \$2,159 (\$719 per person) and a \$1,400 honorarium. The same speaker was also paid \$2,000 in total to speak on Lotrel topics at various doctor’s offices on August 20, 2003; September 10,

2003; December 5, 2003; and December 18, 2003; even though, according to Novartis's data, there were no attendees at any of these programs.

109. Likewise, Novartis conducted the following additional speaker programs on Lotrel topics with astronomical dinner costs:

- A program on February 18, 2005 for three attendees at Sushi Roku in Pasadena, California, with a meal cost of \$1,259 (\$314 per person), and a \$1,000 honorarium for the speaker. Novartis also paid \$500 for a meal for this speaker, along with a \$1,000 honorarium for a program on April 23, 2004 at AOC Restaurant, a wine bar in Los Angeles, at which there were no attendees reported. He was also paid \$1,000 and \$750 respectively for programs on March 20, 2003 and September 30, 2003 at which there were no attendees reported;
- A program on December 12, 2005 for two attendees at Nobu in Dallas, Texas, with a meal cost of \$9,750 (\$3,250 per person);
- A program on January 18, 2006 for four attendees at Swan Lake public garden in Sumter, South Carolina, with a meal cost of \$2,023 (\$404 per person);
- A program on Valentine's Day, February 14, 2006, for two attendees at Fleming's Prime Steakhouse and Wine Bar in West Des Moines, Iowa, with a meal cost of \$3,127 (\$1,042 per person); and
- A program on March 16, 2006 for three attendees at Mahogany, a high-end steakhouse in Oklahoma City, Oklahoma, with a meal cost of \$1,452 (\$363 per person).

110. Many speaker programs were not conducted in private rooms, either because the restaurant did not have one or because Novartis chose not to conduct the program in a private room. For example, a doctor in the Bronx was paid \$500 to speak at Nobu, a famously high-end restaurant in New York City in May 2006 at a dinner attended only by himself, two of his friends, one of whom brought his girlfriend (who was not a health care professional) and a Novartis sales representative. The dinner did not occur in a private room and no slides were presented.



111. In fact, many Novartis speaker programs did not take place in a private room, making it difficult or impossible to hear the speaker or to show slides. When speaker programs occurred in the public space of a restaurant it was common practice not to show the slides.

112. Many Novartis speaker programs were merely social events for the doctors and Novartis sales representatives, who were often friends with each other.

113. Aside from not presenting the slide decks, many of the doctors who participated in Novartis speaker programs did nothing but socialize with their friends at the events. Often the only people who would come to a doctor's programs were people who knew the doctor. Novartis sales representatives understood the situation and would frequently ask speakers whom they should invite. The doctors who were willing to attend programs were often friends with each other who socialized outside the context of speaker programs as well.

114. The conversation at these dinners was generally not about the drug that was the subject of the speaker program. Doctors attended the programs to have dinner together, often at high-end restaurants, and to network with colleagues. They also attended each other's programs to ensure that they would all continue to be paid as Novartis speakers. The doctors knew that if they did not attend each other's events the programs could not take place and none of them would continue to get paid by Novartis.

**IX. Novartis Made Payments to Doctors for Speaker Programs That Did Not Occur or Were Not Attended by the Doctors Novartis Claimed Were Present**

115. In addition, some of the programs for which speakers were paid by Novartis either did not occur at all or did not have the attendees Novartis claims were present. Novartis created phony records regarding these speaker programs to make it appear that they were legitimate, educational programs with an appropriate number of attendees when they were not.

116. For example, the primary speaker in the Brooklyn cluster was seeing patients at her office during the times when Novartis claimed that she was purportedly speaking about Lotrel on March 20, 2007 and April 17, 2007. She was paid an honorarium of \$1,000 for “speaking” on each of those occasions, as well as “ground transportation” expenses, even though she was purportedly speaking at her own office. The purported attendees on these occasions were the exact same attendees that purportedly attended all of her events and whose events she in turn purportedly attended.

117. Novartis also paid honoraria to doctors in West Virginia for speaker programs that did not occur. One of the doctors in the West Virginia cluster was paid for speaking at dinners that he never attended and restaurants that he had never even heard of. According to Novartis’s data, this doctor was paid \$750 to speak at David’s at the Club, a high-end restaurant in Bluefield, West Virginia, on October 6, 2005 to three other doctors in the cluster, on the Lotrel topic “Achieving BP Goal in More Patients by Using More Effective Drug Combinations.” According to Novartis’s data, he also attended several speaker programs at David’s at the Club, including a program on September 29, 2005 for which Novartis paid \$750 to another doctor in the cluster as the speaker, and a program on August 25, 2005 on another Lotrel topic for which Novartis paid \$750 to yet another doctor in the cluster as the speaker.

118. Similarly, Novartis paid honoraria to doctors in Cedar Knolls, New Jersey, for purported speaker programs that did not occur. Novartis’s data indicates that a nurse attended the following speaker programs on Lotrel topics given by one of the doctors in the cluster when she did not attend the programs:

- February 12, 2007 at Sushi Lounge, a restaurant in Morristown, New Jersey;
- May 2, 2007 at 3 West, a restaurant in Basking Ridge, New Jersey; and

- July 9, 2007 at Basilico, a restaurant in Milburn, New Jersey.

119. Likewise, a doctor in the Cedar Knolls cluster also did not attend many of the events that Novartis's records indicate he attended. He attended only one program given by the primary speaker in the Cedar Knolls cluster, but Novartis's speaker program data indicates he attended 14 speaker programs given by that speaker on the following dates:

- February 27, 2006 at Tre Vigne in Bernardsville, New Jersey;
- March 27, 2006 at Cinque Figlie in Whippany, New Jersey;
- April 4, 2006, May 2, 2006, July 21, 2006, October 9, 2006, and May 14, 2007 at the speaker's office in Cedar Knolls, New Jersey;
- August 24, 2006 at Copeland Restaurant in Morristown, New Jersey;
- November 15, 2006 at Grand Café in Morristown, New Jersey;
- February 12, 2007 at Sushi Lounge in Morristown, New Jersey, a restaurant the doctor had never been to;
- May 2, 2007 at 3 West in Basking Ridge, New Jersey, another restaurant the doctor had never been to;
- May 8, 2007 at Medical Institute in Saddle River, New Jersey;
- June 6, 2007 at Serenade in Chatham, New Jersey; and
- July 9, 2007 at Basilico in Milburn, New Jersey.

At the programs in 2007 on February 12, May 2, June 6, and July 9, Novartis's records indicate that he was one of only three attendees, including the nurse referred to in paragraph 118 above.

120. The same doctor also did not attend the following events that Novartis's records claim he attended at which another doctor was the purported speaker:

- April 19, 2004 and May 8, 2007 at The Medical Institute in Cedar Knolls, New Jersey;
- October 6, 2004 at Cheeseblock in Cedar Knolls, New Jersey;

- August 31, 2005 at an unspecified office in Cedar Knolls, New Jersey;
- April 25, 2005 and November 8, 2005 at a doctor's office at 11 Saddle Road in Cedar Knolls, New Jersey;
- April 11, 2006 at an unspecified location in Cedar Knolls, New Jersey; and
- September 28, 2006 at his office in Cedar Knolls, New Jersey.

121. Novartis also paid a doctor in another cluster in the Toms River area in New Jersey an honorarium of \$1,500 for a speaker program that did not occur. According to Novartis's data, the program was on Friday, August 4, 2006, in Toms River, New Jersey, at a location reported as "TBD," with a meal cost of \$1 and was purportedly attended by three doctors, two of whom purportedly attended the same program multiple times. Based on Novartis's own data, this event did not occur, yet an honorarium was paid for it.

**X. Novartis Paid Doctors Honoraria and Wined and Dined Them to Induce the Doctors to Write Prescriptions for Novartis Drugs**

122. As Novartis found every year starting in 2004, speaker programs had a good return on investment. Novartis's Business Analysis Unit in 2004 reported that "[s]peaker programs for most brands exceed or approach break even after only 5 months and results are expected to improve through [the] year." The "best returns" were on doctors who wrote the highest numbers of prescriptions for Novartis drugs before participating in Novartis's speaker programs, known as "Tier 1" doctors, but "good returns are also possible for the lowest tier," according to Novartis's Business Analysis Unit, which was responsible for measuring the return on investment for speaker programs, among other promotional events.

123. As Paul Rabideau, Novartis's Senior Director of Marketing and Sales Analytics put it, no matter what "tier" a doctor was in he or she could be influenced, and "Tier 1" doctors are more profitable because they start off with a higher prescription base.

124. Novartis intended that the more incentives doctors received in the form of meals, entertainment, and honoraria, the more the doctors would write prescriptions for Novartis drugs. In a “Meeting and Events Analysis” dated November 9, 2004, Novartis’s Business Analysis Team noted that “Offering an honorarium is the top factor across all classes” of drugs driving the return on investment with respect to promotional programs. The Business Analysis Unit concluded in 2004 that if a doctor would not attend a “round table” program, which was cheaper for Novartis because no one had to be paid an honorarium, then “invite [the doctor] to the most expensive speaker program.”

125. In May 2006, Novartis found that speaker programs in 2005 for Lotrel had a return on investment of more than 1.39, meaning that for every dollar spent on the programs, Novartis made more than \$1.39 in revenue on the increase in prescriptions written by these doctors as compared to a control group of doctors who did not participate in speaker programs. For the highest prescribers, the Tier 1 doctors, the return on investment was 2.52, meaning that these doctors wrote an additional \$2.52 in prescriptions for Lotrel for every dollar Novartis spent on the programs in which they participated. For Tier 2 doctors, the return on investment was even higher – 2.77 – while for Tier 3 doctors, it was 1.57. Moreover, according to Mr. Rabideau, the return on investment from speaker programs increased over time up to 18 months after each speaker program.

126. Novartis used its speaker programs to drive prescriptions and doctors knew it. Sales representatives chose doctors to be speakers based on high levels of prescriptions, which the doctors had to maintain or increase in order to continue to be invited to present programs.

127. Moreover, individual doctors' writing of prescriptions for Novartis drugs closely tracks the dates on which the doctors received payments to speak about the drugs. Once a doctor became a speaker, Novartis closely followed the doctor's prescribing habits.

128. For example, according to Novartis's speaker program data, a doctor in one of the Pittsburgh clusters received honoraria for speaking about Lotrel beginning in May 2003 and continuing through May 2007. During that period, the number of prescriptions he wrote for Lotrel increased greatly, with the highest levels of prescriptions corresponding to the periods in which he received the largest payments from Novartis, including September 2004 through May 2005 and January 2006 through May 2007.

129. Likewise, a doctor in the West Virginia cluster greatly increased the number of Lotrel prescriptions that he wrote after he began receiving honoraria from Novartis in May 2005 to speak about Lotrel. The number of prescriptions he wrote continued to increase thereafter, tracking increases in the honoraria he was paid, during the period from May 2005 through January 2007. Subsequently, as his honoraria payments leveled off, the number of prescriptions he wrote for Lotrel began to decline and, after September 2007, when he stopped receiving honoraria related to Lotrel, they declined dramatically and then stopped altogether.

130. Similarly, a doctor in the East Orange, New Jersey, cluster who often did not show slides increased the number of prescriptions she wrote for Lotrel after she started receiving honoraria for speaking about the drug in May 2005, and the number of prescriptions she wrote increased to their highest levels during the period from May 2006 through May 2007, when she was receiving the largest honoraria payments from Novartis. After May 2007, when she stopped receiving honoraria for Lotrel programs, the number of prescriptions she wrote for Lotrel

declined sharply. Moreover, the number of prescriptions she wrote for Valtorna also increased dramatically after she began receiving honoraria from Novartis in September 2009.

131. Another doctor in that same cluster who also showed few or no slides similarly wrote his highest levels of prescriptions for Lotrel during the period in May 2006, after he began receiving honoraria from Novartis for speaker programs regarding the drug, and far fewer in May 2007, when he stopped. In addition, the number of prescriptions he wrote for Valtorna increased sharply after he began receiving honoraria for speaking about that drug in the period September 2009 through September 2010 and fell off dramatically thereafter.

132. Novartis sales representatives had strong incentives to use speaker programs to reward doctors for writing prescriptions or to induce them to increase their number of prescriptions, because sales representatives were compensated in part based on how many prescriptions those doctors wrote. The pressure Novartis placed on sales representatives to increase sales was evident to the doctors.

#### **XI. Novartis's Compliance Program Was Inadequate to Prevent Fraud with Respect to Its Speaker Programs**

133. Even after Novartis entered into a CIA with the Office of Inspector General of the Department of Health and Human Services in September 2010, its compliance program included insufficient controls to prevent speaker programs from being used as a vehicle for kickbacks to doctors through the payment of honoraria or lavish dinners and entertainment. Novartis had no controls to prevent sales representatives from hosting programs in which the same doctors spoke repeatedly to the same attendees on exactly the same topic.

134. Nor did Novartis have sufficient controls to ensure that speaker programs were occurring as claimed by the sales representatives and recorded in Novartis's speaker program platform. Sales representatives recorded data regarding the attendees at each program in that

platform. Considering that sales representatives could benefit financially by paying kickbacks to doctors on their call list, this system for ensuring that programs occurred as documented created incentives for abuse. Novartis often did not even require purported attendees at speaker events to sign the attendance sheets at the programs.

135. Speaker program data was available to and, according to Mr. Puckowitz, was sent by sales representatives up the supervisory chain of authority in Novartis's sales force.

136. Novartis management was made aware of the inadequacies in its existing compliance programs and the numerous violations of it that occurred.

137. In fact, Novartis's board of directors was informed of significant compliance issues on March 19, 2009 at a presentation entitled "Representatives [sic] Interactions With Healthcare Professionals," given by the Executive Director of Ethics and Compliance and the Director of Regulatory Compliance. The presentation included the following findings regarding speaker programs:

- "Discrepancies existed between attendees physically present, attendees per Sign In Sheets and attendees per Event Alliance [the speaker program database] records;"
- "Frequent utilization of venues not conducive to a private business meeting;"
- "An insufficient number of HCPs (<3) in attendance at programs;"
- "Excessive meal and alcohol costs at Field Managed Promotional Speaker Events . . . primarily due to a lack of responsibility for reviewing itemized meal receipts;"
- "Lack of responsibility to monitor the speaker's performance in presenting the approved materials;" and
- "Inappropriate speaker conduct and non-compliance with policies."

138. Despite being aware of these issues, Novartis's response remained inadequate.

139. Moreover, as a result of the monitoring it was required to conduct pursuant to the CIA, Novartis knew or should have known that its speaker programs continued to be plagued



with problems. Novartis's E&C department, which is responsible for conducting internal audits and investigations of violations of Novartis policies, among other things, monitored only 107 out of thousands of speaker programs in 2011. In each case, Novartis gave notice to the sales representatives hosting the program that a monitor would be attending. Even with a monitor present, the E&C department found that in 44 of the 107 programs monitored – over 40% – there were violations of the “modest meal” policy. In eight out of the 107 programs monitored, despite the presence of the monitor, the “[s]peakers did not present the entire slide deck (skipped some slides).” Moreover, “the host representatives did not ensure the required slides were presented.” In addition, at 35 of the programs – approximately 33% – the monitor found “inconsistencies with supporting documentation, the most common being the names and number of attendees on the sign in sheet not matching the names and number of attendees recorded in the Event Alliance system.”

140. The director of the E&C department, concluded that, based on these and other violations of Novartis's policies, sales representatives “didn't understand their roles” in ensuring that speaker programs were compliant. However, Novartis's primary response to the problem was to hold a webinar training of sales representatives in January 2012. Novartis did not increase its monitoring of speaker programs, schedule unannounced visits to programs, or interview any doctors who had purportedly participated in speaker programs in response to the problem.

141. A report from the Ethics and Compliance department to Novartis's Board of Directors on March 9, 2011, indicated that out of 22 speaker programs the E&C department had monitored in the fourth quarter of 2010, the speaker did not present slides at three programs and at eight programs the monitor observed violations of the meal policy. Again, these violations

occurred even though the monitor informed the sales representative hosting the program ahead of time that it would be audited.

142. Moreover, when Novartis made findings of speaker program fraud, it imposed sanctions that were mere slaps on the wrist. For example, according to data compiled by the E&C department, an anonymous call was placed to Novartis's Compliance Alertline in 2009 alleging that a sales representative "was paying off doctors to achieve higher sales numbers." The E&C department found that "[a]fter an extensive review of [the representative's] expenses as well as speaker programs, it was revealed that [the representative] paid for [a particular doctor, Dr. #1] to speak eight (8) times in 2008. The same attendees were present for each program." Novartis's investigator also found that the sales representatives had "utilized another doctor [Dr. #2] . . . who only spoke twice, but also had the same six attendees present for both programs, including [Dr. #1]. Dr. #2 was present for six (6) days of [Dr. #1's] programs in 2008." However, Novartis's E&C department apparently did not view these problems with repeat attendees as worthy of any response. The only disciplinary action the department recommended for the sales representative was "verbal coaching" regarding "control over alcohol expenses," based on the large amount of alcohol (such as five bottles of wine for five attendees) that were purportedly purchased at many of the events.

143. Similarly, the E&C department made findings of other conduct indicative of kickbacks. In one instance, Novartis's E&C department became aware that a sales representative had hosted a speaker program in Montego Bay, Jamaica, in 2008 that cost \$15,000 and was attended by only two Novartis employees and one health care professional. The sales representative who hosted the program was not terminated. The only punishment the sales representative received was reportedly a "conduct memo."

144. Likewise, according to Novartis's data, the E&C department made findings in April 2011, after the CIA was signed, that in 2009 a sales representative held a promotional lunch for \$467 at a sports bar that was "more of a bar/karaoke night club" than a restaurant, with no Novartis employees present and "no medically relevant discussion." The only discipline this sales representative received was a "conduct memo."

## **XII. In Addition to Lotrel, Valturna and Starlix, Novartis Conducted Fraudulent Speaker Programs With Respect to Other Drugs**

145. As discussed in Section V above, in addition to Lotrel, Valturna, and Starlix, during the period from January 2002 through at least November 2011, Novartis also promoted Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge, and Exforge HCT as part of its cardiovascular division. Although, as relevant to this complaint, the September 2010 settlement released claims related to speaker program fraud for the drugs Diovan, Tekturna, and Exforge through December 31, 2009, the settlement, by its terms, did not release claims for Tekamlo or for any of the HCT forms of these drugs. Numerous speaker programs occurred with respect to Tekamlo and the HCT forms of Diovan, Tekturna and Exforge throughout the time period relevant to this complaint.

146. Moreover, Novartis continued to conduct speaker programs on Diovan, Tekturna, and Exforge after December 31, 2009, through at least the end of 2011. In August, 2010 a doctor reported to Impact Rx, a Novartis vendor specializing in healthcare marketing, that a Novartis "rep stopped by to invite me to a [Diovan] dinner meeting tomorrow night." In December, 2011 another doctor, discussing a Novartis representative's promotion of Diovan HCT, reported that the representative "invited me to attend a speaker program." Likewise, another doctor reported that a "[r]epresentative came by dropping off [Tekturna] samples, and invited me to dinner with my spouse."

**XIII. Novartis Caused Thousands of False Claims to be Submitted to and Paid For by Federal Health Care Programs**

147. Novartis caused many thousands of prescriptions to be written as a result of speaker programs that were kickbacks to doctors. Novartis paid at least 26,997 doctors kickbacks in the form of honoraria and/or exorbitant meals and entertainment in conjunction with speaker programs on Lotrel, Valtorna, and Starlix during the period from January 2002 through November 2011. On average each of these doctors wrote many thousands of dollars' worth of prescriptions for Lotrel, Valtorna, and Starlix that were reimbursed or purchased by federal health care programs.

148. For example, after Novartis started paying her as a speaker on Lotrel, a doctor in the East Orange, New Jersey cluster who participated in Novartis's speaker program fraud wrote \$39,793 in prescriptions for Lotrel, Valtorna, and Starlix that were reimbursed by Medicare. She also wrote \$1,622 in prescriptions for Tekamlo, as well as \$160,174 in prescriptions for Diovan, Tektorna, and Exforge that were reimbursed by Medicare after January 1, 2010.

149. Similarly, after Novartis began paying him as a speaker on Lotrel, a doctor in the Bronx who participated in Novartis's speaker program fraud wrote \$14,509 worth of prescriptions for Lotrel, Valtorna, and Starlix, and \$544 in prescriptions for Tekamlo that were reimbursed by Medicare, as well as \$26,510 in prescriptions for Diovan, Tektorna, and Exforge that were reimbursed by Medicare after January 1, 2010.

150. Similarly, after Novartis began paying him as a speaker on Lotrel, one of the doctors in the West Virginia cluster who participated in Novartis's speaker program fraud wrote \$4,286 in prescriptions for Lotrel and Starlix that were reimbursed by Medicare, as well as \$6,377 in prescriptions for Diovan that were reimbursed by Medicare after January 1, 2010.

151. Novartis is liable to the federal government for damages based on payment of these claims.

152. By way of example, from 2001 to 2011, Novartis's illegal kickbacks to doctors discussed in the preceding paragraphs caused the false claims noted below to be submitted to federal health care programs. Each of these doctors received illegal remuneration from Novartis in the form of speaker honoraria or lavish dinners and entertainment and thereafter submitted claims to the Medicare program.

Lotrel		
Physician	No. of Medicare Claims	Medicare Payment
Dr. A (Bronx, NY)	331	\$11,161
Dr. B (East Orange, NJ)	343	\$20,434
Dr. C (East Orange, NJ)	204	\$14,279
Dr. D (Beckley, WV)	80	\$2,913
Dr. E (Beckley, WV)	287	\$13,153
Dr. F (Union, NJ)	137	\$1,470
Dr. G (Pittsburgh, PA)	289	\$5,613
Dr. H (Pittsburgh, PA)	565	\$5,923
Dr. I (Bethlehem, PA)	174	\$3,997
Dr. J (Rockford, IL)	374	\$8,779
Dr. K (Rockford, IL)	157	\$2,850
Dr. L (Edgewater, NJ)	126	\$3,137
Dr. M (Edgewater, NJ)	962	\$64,225

Valturna		
Physician	No. of Medicare Claims	Medicare Payment
Dr. A (Bronx, NY)	62	\$3,264
Dr. B (East Orange, NJ)	150	\$4,016
Dr. C (East Orange, NJ)	73	\$4,658
Dr. K (Rockford, IL)	56	\$1,757
Dr. L (Edgewater, NJ)	126	\$4,631
Dr. M (Edgewater, NJ)	139	\$7,243

Starlix		
Physician	No. of Medicare Claims	Medicare Payment
Dr. B (East Orange, NJ)	213	\$15,343
Dr. C (East Orange, NJ)	86	\$5,757
Dr. D (Beckley, WV)	24	\$1,373
Dr. F (Union, NJ)	431	\$16,941
Dr. H (Pittsburgh, PA)	17	\$1,005
Dr. J (Rockford, IL)	148	\$6,614
Dr. M (Edgewater, NJ)	54	\$5,283

153. Doctors A-M were part of the aforementioned clusters described in Section VII, and a summary of the honoraria these doctors each received for speaking on Lotrel, Valtorna, and Starlix is below.

Doctor	Lotrel Honoraria	Valturna Honoraria	Starlix Honoraria	Total Honoraria
Dr. A	\$6,750	\$11,250		\$18,000
Dr. B	\$29,600	\$12,500	\$4,750	\$46,850
Dr. C	\$14,500	\$2,250		\$16,750
Dr. D	\$9,000			\$9,000
Dr. E	\$9,250	\$7,750		\$17,000
Dr. F	\$21,850	\$10,250	\$7,500	\$39,600
Dr. G	\$15,000			\$15,000
Dr. H	\$33,400	\$1,250		\$34,650
Dr. I	\$6,750	\$13,250		\$20,000
Dr. J	\$2,500			\$2,500
Dr. K	\$7,000	\$6,750		\$13,750
Dr. L	\$9,200	\$14,250		\$23,450
Dr. M	\$7,750	\$17,500		\$25,250

154. Compliance with the Anti-Kickback Statute is a precondition of payment by virtue of federal and state statutes, regulations, and provider agreements.

155. The certifications in provider agreements are representations of compliance with the Anti-Kickback Statute. Kickbacks that were paid to physicians as alleged herein render those certifications false.

156. Claims for Novartis's prescription drugs arising from the kickbacks expressly and impliedly misrepresent compliance with a material condition of payment, to wit, compliance with the AKS.

157. By providing remuneration to physicians and other health care professionals, Novartis intended to induce those physicians to prescribe certain of Novartis's drugs. It was reasonably foreseeable that some of those prescriptions would be for federal health care program beneficiaries and that claims for those prescriptions would be submitted to federal health care programs. Thousands of such prescriptions were, in fact, submitted to and reimbursed by federal health care programs.

### **FIRST COUNT**

#### **Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a) (1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))**

158. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

159. The United States seeks relief against defendant under Section 3729(a)(1) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

160. As a result of Novartis's kickbacks to induce doctors to prescribe Novartis drugs in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), false and fraudulent claims for payment based on these prescriptions were made to federal health care programs. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

161. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

## **SECOND COUNT**

### **Violations of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))**

162. The United States incorporates by reference paragraphs 1 through 157 as if fully set forth herein.

163. The United States seeks relief against defendants under the False Claims Act, 31 U.S.C. § 3729(a)(2)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

164. As a result of Novartis's kickbacks to induce doctors to prescribe Novartis drugs in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), Novartis knowingly caused doctors to make false records or statements that were material to false or fraudulent claims for payment submitted to federal health care programs. The false records or statements were the doctors' false certifications and representations of full compliance with all federal and state laws and regulations prohibiting fraudulent and false reporting, including but not limited to the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

165. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

## **THIRD COUNT**

### **Unjust Enrichment**

166. The United States incorporates by reference each of paragraphs 1 through 157 as if fully set forth in this paragraph.



167. The United States paid claims submitted to federal health care programs for reimbursement for Novartis drugs based on false statements submitted to federal health care programs as a result of Novartis's violations of applicable federal and state laws and regulations, including the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. The circumstances of Novartis's receipt of payments based on the prescriptions written by doctors who received kickbacks are such that, in equity and good conscience, Novartis should not retain those payments, the amount of which is to be determined at trial.

WHEREFORE, the United States respectfully requests judgment against Novartis as follows:

- a. On Counts One and Two (FCA) a judgment against Novartis for treble damages and civil penalties for the maximum amount allowed by law;
- b. On Count Three (common law) a judgment for damages to the extent allowed by law.

Dated: April 26, 2013  
New York, New York

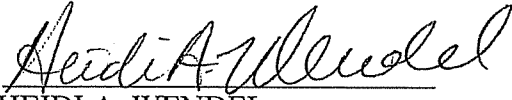
Respectfully submitted,

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